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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,955	05/27/1999	KRISTIN M. LUNDY	PC9808A	6904

7590

06/05/2003

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,955

Applicant(s)

LUNDY ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,15-23 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The following is responsive to Applicant's amendment received Jan. 17, 2003.

Claims 5, 8-14, 24-25, 26-33 are cancelled without prejudice or disclaimer. No new claims are added. Claims 1, 4, 15-23, 34-36 are currently pending. Claims 34-36 continue to be withdrawn from consideration as being directed to a non-elected invention. (Please see paragraph 9 of the office action mailed Nov. 4, 2002).

All previous claim objections and rejections set forth in paragraphs 10-21 of the office action mailed Nov. 4, 2002 as well the rejections maintained in the office action mailed Nov. 4, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The allowability of claim 1 is withdrawn in view of the new grounds of rejection submitted hereinbelow.

Finally, the finality of the office action mailed Nov. 4, 2002 is withdrawn in view of the following new ground of rejection. Prosecution on the merits is reopened.

New Ground(s) of Rejection

Claim Objections

1. Claim 4 is objected to because of the following informalities: in claim 4, lines 10-11, the phrase "selected from the group consisting essentially of" should read --selected from the group consisting of--. The term "essentially" should be cancelled. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

2. Claims 1, 4, 15-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to method of treating or preventing inflammatory diseases associated with the activity of COX-2 in a member of the species of *Canis familiaris* by administering an effective amount of the compounds encompassed by Formula (I). The claimed methods of treatment or prevention fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "inflammatory diseases associated with the activity of inducible COX-2." Furthermore, the claimed methods require treatment of an unspecified disease and no evidence indicates that a treatable disease was known to Applicant. In the absence of some understanding of the disease to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods.

3. Claims 1, 4, 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "inflammatory diseases associated with COX-2 inhibition renders the claims vague and indefinite. Upon reference to Applicant's specification, the Examiner is unable to locate a description of what is meant by or what is encompassed by

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such a limitation. As a result, one of ordinary skill in the art would not be readily apprised of the scope of the claims. Thus, the metes and bounds of the patent protection desired is unclear.

Conclusion

Claims 1, 4, 15-23 are rejected.

Claims 34-36 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

June 3, 2003


DWAYNE C. JONES
PRIMARY EXAMINER